

APPENDIX

PENDING CLAIMS

1 1. A system for averting undesirable pharmacokinetic drug interaction
2 between a drug and concomitant drug(s), which comprises controlling the *in vivo* release time
3 and/or release site of the drug and/or the concomitant drug(s).

1 2. A system for averting undesirable drug interaction between a drug and
2 concomitant drug(s), both of which use the same route in terms of *in vivo* drug absorption,
3 distribution, metabolism or excretion in humans, which comprises controlling the *in vivo* release
4 time and/or release site of the drug and/or the concomitant drug(s).

1 3. A system for averting undesirable drug interaction between a drug and
2 concomitant drug(s), both of which are metabolized by the same molecular species of drug-
3 metabolizing enzyme in humans, or between a drug and concomitant drug(s) that is metabolized
4 by the molecular species of drug-metabolizing enzymes that is inhibited by the said drug, which
5 comprises timed-release control of the said drug or control of the site of release of the said drug
6 to the digestive tract.

1 4. A system for averting undesirable drug interaction between a drug and
2 concomitant drug(s), both of which metabolized by the drug metabolizing enzyme CYP3A4, or
3 between a drug that inhibits CYP3A4 and concomitant drug(s) that is metabolized by CYP3A4,
4 which comprises timed-release control of the said drug or controlling release specifically in the
5 lower digestive tract of the said drug.

1 5. A drug preparation for averting undesirable pharmacokinetic drug
2 interaction between a drug and concomitant drug(s), which comprises controlling the *in vivo*
3 release time and/or release site of the said drug.

1 6. A drug preparation for averting undesirable drug interaction between a
2 drug and concomitant drug(s), both of which use the same route in terms of *in vivo* drug
3 absorption, distribution, metabolism or excretion in humans, which comprises controlling the *in*
4 *vivo* release time and/or release site of the said drug.

1 7. A drug preparation for averting undesirable drug interaction on the *in vivo*
2 kinetics of a drug by concomitant drug(s) that inhibits *in vivo* metabolism of the said drug in
3 humans, which comprises timed-release control of the concomitant drug or control of the site of
4 release of the concomitant drug to the digestive tract.

1 8. A drug preparation for averting undesirable effects on the blood
2 concentration of a drug by concomitant drug(s) that inhibits the *in vivo* metabolism of the said
3 drug by CYP3A4 in humans, which comprises timed release control of the said drug or
4 controlling release specifically in the lower digestive tract of the concomitant drug.

1 9. The drug preparation according to Claim 8, whereby the said drug and the
2 concomitant drug are a combination selected from anfentanyl, fentanyl, sulfentanyl, cocaine,
3 dihydrocodeine, oxycodone, tramadol, erythromycin, clarithromycin, troleandomycin,
4 azithromycin, itraconazole, ketoconazole, dapsone, midazolam, triazolam, alprazolam, diazepam,
5 zolpidem, felodipine, nifedipine, nitrendipine, amlodipine, isradipine, nicardipine, nimodipine,
6 nisoldipine, nildipine, bepridil, diltiazem, verapamil, astemizole, terfenadine, loratidine,
7 cyclosporine, tacrolimus, rapamycin, amiodarone, disopyramide, lidocaine, propafenone,
8 quinidine, imipramine, amitriptyline, clomipramine, nafazodone, sertraline, trazodone,
9 haloperidol, pimozide, carbamazepine, ethosuximide, trimethadione, simvastatin, lovastatin,
10 fluvastatin, atorvastatin, etoposide, ifosfamide, paclitaxel, tamoxifen, taxol, vinblastine,
11 vincristine, indinavir, ritonavir, saquinavir, testosterone, prednisolone, methylprednisolone,

12 dexamethasone, proguanil, warfarin, finasteride, flutamide, ondasteron, zatsetrone, cisapride,
13 cortisol, zonisamide, desmethyldiazepam, and conivaptan.

1 10. A method for averting undesirable pharmacokinetic drug interaction
2 between a drug and concomitant drug(s), comprising administering to patients a drug preparation
3 with which the *in vivo* release time and/or release site of the said drug is controlled.

1 11. A method for averting undesirable drug-interaction between a drug and
2 concomitant drug, both of which use the same route in terms of *in vivo* drug absorption,
3 distribution, metabolism or excretion in humans, comprising administering to patients a drug
4 preparation with which the *in vivo* release time and/or release site of the said drug is controllable.

1 12. A method for averting undesirable drug-interaction on the *in vivo* kinetics
2 of a drug by concomitant drug that inhibits the *in vivo* metabolism of the said drug by drug-
3 metabolizing enzymes in humans, comprising administering to patients a drug preparation with
4 which timed-release of the concomitant drug or release site of the concomitant drug to the
5 digestive tract is controllable.

1 13. A method for averting undesirable effects on the blood concentration of a
2 drug by concomitant drug that inhibits the *in vivo* metabolism of the said drug by CYP3A4,
3 comprising administering to patients a drug preparation with which timed-release of the
4 concomitant drug or release of the concomitant drug specifically to the lower digestive tract is
5 controllable.

1 14. The method according to Claim 13, whereby the said drug and the
2 concomitant drug are a combination selected from anfantanyl, fentanyl, sulfentanyl, cocaine,
3 dihydrocodeine, oxycodone, tramadol, erythromycin, clarithromycin, troleandomycin,
4 azithromycin, itraconazole, ketoconazole, dapsone, midazolam, triazolam, alprazolam, diazepam,

5 zolpidem, felodipine, nifedipine, nitrendipine, amlodipine, isradipine, nicardipine, nimodipine,
6 nisoldipine, nildipine, bepridil, diltiazem, verapamil, astemizole, terfenadine, loratidine,
7 cyclosporine, tacrolimus, rapamycin, amiodarone, disopyramide, lidocaine, propafenone,
8 quinidine, imipramine, amitriptyline, clomipramine, nafazodone, sertraline, trazodone,
9 haloperidol, pimozone, carbamazepine, ethosuximide, trimethadione, simvastatin, lovastatin,
10 fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel, tamoxifen, taxol, vinblastine,
11 vincristine, indinavir, ritonavir, saquinavir, testosterone, prednisolone, methylprednisolone,
12 dexamethasone, proguanil, warfarin, finasteride, flutamide, ondasteron, zatsetrone, cisapride,
13 cortisol, zonisamide, desmethyldiazepam, and conivaptan.

1 15. A system for averting undesirable pharmacokinetic interaction between a
2 drug and food(s), which comprises controlling the *in vivo* release time and/or release site of the
3 drug.

1 16. (New) A drug preparation for averting undesirable effects on the blood
2 concentration of a drug by concomitant drug(s) that inhibits the *in vivo* metabolism of the said
3 drug by CYP3A4 in humans, which comprises timed release control of the said drug or
4 controlling release specifically in the lower digestive tract of the concomitant drug, whereby:
5 the said drug and the concomitant drug are a combination selected from
6 anfantanyl, fentanyl, sulfentanyl, cocaine, dihydrocodeine, oxycodone, tramadol, erythromycin,
7 clarithromycin, troleandomycin, azithromycin, itraconazole, ketoconazole, dapson, midazolam,
8 triazolam, alprazolam, diazepam, zolpidem, felodipine, nifedipine, nitrendipine, amlodipine,
9 isradipine, nicardipine, nimodipine, nisoldipine, nildipine, bepridil, diltiazem, verapamil,
10 astemizole, terfenadine, loratidine, cyclosporine, tacrolimus, rapamycin, amiodarone,
11 disopyramide, lidocaine, propafenone, quinidine, imipramine, amitriptyline, clomipramine,
12 nafazodone, sertraline, trazodone, haloperidol, pimozone, carbamazepine, ethosuximide,
13 trimethadione, simvastatin, lovastatin, fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel,
14 tamoxifen, taxol, vinblastine, vincristine, indinavir, ritonavir, saquinavir, testosterone,

15 prednisolone, methylprednisolone, dexamethasone, proguanil, warfarin, finasteride, flutamide,
16 ondansteron, zatsetrone, cisapride, cortisol, zonisamide, desmethyldiazepam, and conivaptan.

1 17. (New) A drug preparation for averting undesirable drug interaction on the
2 *in vivo* kinetics of a drug by concomitant drug(s) that inhibits *in vivo* metabolism of the said drug
3 in humans, which comprises timed-release control of the concomitant drug or control of the site
4 of release of the concomitant drug to the digestive tract whereby:

5 the said drug and the concomitant drug are a combination selected from
6 anfantanyl, fentanyl, sulfentanyl, cocaine, dihydrocodeine, oxycodone, tramadol, erythromycin,
7 clarithromycin, troleandomycin, azithromycin, itraconazole, ketoconazole, dapsone, midazolam,
8 triazolam, alprazolam, diazepam, zolpidem, felodipine, nifedipine, nitrendipine, amlodipine,
9 isradipine, nicardipine, nimodipine, nisoldipine, nildipine, bepridil, diltiazem, verapamil,
10 astemizole, terfenadine, loratidine, cyclosporine, tacrolimus, rapamycin, amiodarone,
11 disopyramide, lidocaine, propafenone, quinidine, imipramine, amitriptyline, clomipramine,
12 nafazodone, sertraline, trazodone, haloperidol, pimozone, carbamazepine, ethosuximide,
13 trimethadione, simvastatin, lovastatin, fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel,
14 tamoxifen, taxol, vinblastine, vincristine, indinavir, ritonavir, saquinavir, testosterone,
15 prednisolone, methylprednisolone, dexamethasone, proguanil, warfarin, finasteride, flutamide,
16 ondansteron, zatsetrone, cisapride, cortisol, zonisamide, desmethyldiazepam, and conivaptan.